THE EMBODIMENTS OF THE INVENTION IN WHICH AN EXCLUSIVE PROPERTY OR PRIVILEGE IS CLAIMED ARE DEFINED AS FOLLOWS:

1. An inhalable, stable formulation comprising methacholine chloride at a concentration of from 0.025 to 25 mg/ml dissolved in a buffer solution having a pH in the range of about 4 to about 5.

2. The formulation according to claim 1, wherein the pH of the buffer solution is in the range of about 4.5 to about 5.0.

3. The formulation according to claim 1, wherein the pH of the buffer solution is in the range of about 4.5 to about 4.7.

4. The formulation according to claim 1, wherein the buffer solution is an acetate or citrate buffer solution.

5. The formulation according to claim 4, wherein the acetate buffer solution has an acetate concentration of about 4.5 to about 8.5 mM.

6. The formulation according to claim 5, wherein the acetate concentration is about 4.8 mM.

7. The formulation according to claims 1, which has been filter sterilized by aseptic filtration.

8. The formulation according to claim 1, which additionally comprises a preservative.

9. The formulation according to claim 1, which additionally comprises sodium chloride.

10. The formulation according to claim 1, which is provided in a sealed container.

11. The formulation according to claim 10, wherein the sealed container comprises a stopper.

12. The formulation according to claim 1 for use in bronchoprovocation testing.

13. A method of preparing the formulation according to claim 1 comprising the steps of:
    (a) dissolving methacholine chloride in the buffer solution; and
    (b) filter sterilising the solution formed in step (a) using aseptic filtration.

14. The method according to claim 13, additionally comprising the step of preparing the buffer solution prior to step (a) by dissolving a buffer agent in water and, optionally, adjusting the pH to within the range of about 4 to about 5.

15. The method according to claim 14, wherein the buffer agent is acetate, or a pharmaceutically acceptable salt thereof.

16. The method according to 15, wherein the buffer solution has an acetate concentration of about 4.5 to about 8.5 mM.

17. The method according to claim 16, wherein the acetate concentration is about 4.8 mM.

18. The method according to claim 14, wherein the buffer agent is citrate, or a pharmaceutically acceptable salt thereof.

19. A packaged pharmaceutical product comprising a formulation according to claim 1 in a sealable container.

20. The packaged pharmaceutical product according to claim 19, wherein the container is a vial or an ampoule constructed of materials generally accepted for pharmaceutical preparations.

21. The packaged pharmaceutical product according to claim 20, wherein vial is sealed using a suitable closure system to ensure sterility.

22. A method for performing bronchoprovocation testing on a subject comprising the step of administering the formulation according to claim 1 to the subject.

23. A method for determining the amount of methacholine chloride present in a sample comprising the steps of:

(a) injecting an aliquot of the sample into a high pressure liquid chromatography (HPLC) column;

(b) monitoring the eluent from the HPLC column and estimating a peak area for methacholine from the sample;

(c) injecting an aliquot of a standard solution of methacholine chloride into the HPLC column, which standard solution contains a known concentration of methacholine chloride;

(d) monitoring the eluent from the HPLC column and estimating a peak area for methacholine from the standard solution; and, subsequently,

(e) calculating from the peak areas obtained in steps (b) and (d) the amount of methacholine chloride in the sample,

wherein, the HPLC column is a reverse phase column and the column is eluted using a mobile phase comprising tetramethylammonium chloride.

24. The method according to claim 23, wherein the mobile phase consists of a mobile phase consisting of a solution of 1-heptanesulfonic acid sodium, potassium phosphate and tetramethylammonium chloride in water containing 12% (v/v) methanol.

25. The method according to claim 24, wherein the potassium phosphate is potassium phosphate monobasic.

26. The method according to claim 23, wherein steps (a) to (d) are repeated, the estimated peak areas for the sample are used to calculate an average peak area for the sample, the estimated peak areas for the standard solution are used to calculate an average peak area for the standard solution and step (e) is performed using the average peak areas.